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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/833,134 | 04/11/2001 | Leo J. Romanczyk JR. | 5677-111 | 1617 |

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| EXAMINER |
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TATE, CHRISTOPHER ROBIN

| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 07/16/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/833,134

Applicant(s)
Romanczyk JR et al.

Examiner
Christopher Tate

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 22, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-18, and 20-28 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 12-14, and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 5-11, 15-18, and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission (including claim amendments and cancellations) filed on May 22, 2003 has been entered.

Claims 2, 5-11, 15-18, and 20-23 are presented for examination on the merit. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 102

Claims 2, 5, 6, and 9-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by El-Saied et al. (Zeitschrift Fuer Erna., 1981) for the reasons set forth in the previous Office action which are restated below.

El-Saied et al. teach a fat (which reads upon an oil firstly because oil is naturally present in fat and, thus, fat is inherently comprised of oil; and secondly because fat is defined as "a solidified animal or plant oil" -Webster's II New Riverside University Dictionary, 1988) which contains phytosterols such as those instantly claimed obtained from cocoa shells via hexane extraction followed by evaporation of the hexane therefrom, and that, based upon

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chromatographic analyses, the cocoa shell fat was similar in composition to cocoa butter (see, e.g., pages 145-146, Materials and Methods; and pages 149-150 under the heading *Unsaponifiable matter composition*). Based upon the teachings of the instant disclosure (see, e.g., claim 16), the reference cocoa shell fat (oil) obtained by hexane extraction would inherently comprise the recited free and bound phytosterols and tocopherols therein since hexane is disclosed (see, e.g., claim 16) to be a suitable solvent for extracting these naturally-occurring constituents in producing the claimed cocoa shell oil.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 2 and 5-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Baskakova et al. (SU 1734748 - DWPI Abstract), or by Gavrilenko (Maslo-Zhir. Prom-st., 1977 - CAPLUS Abstract) for the reasons of record which are restated below.

Baskakova et al. teach a cocoa husk (hull) oil which is added to a cosmetic formulation (see abstract). The cocoa husk (hull) oil taught by Baskakova would inherently contain the phytosterols and tocopherols instantly claimed since these are natural constituents of cocoa husk oil.

Gavrilenko teaches an oil extracted from cocoa husk (hulls) which does not contain an extraction solvent (see abstract). The crude and refined cocoa husk oil taught by Gavrilenko would inherently contain the phytosterols and tocopherols instantly claimed since these are natural constituents of cocoa husk (hull) oil.

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[With respect to the two cited references, please note that the patentability of a product does not depend on its method of production (see, e.g., MPEP 2113).]

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

Claims 2, 5-11, 15-18, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Saied et al. (Zeitschrift Fuer Ern., 1981), in view of Mueller (J. Dairy Sci., 1959) and Alander et al. (WO 99/63031), and further in view of Newton (EP 0861600).

The primary reference is relied upon for the reasons set forth above.

El-Saied et al. does not expressly teaches grinding the cocoa hulls prior to extraction nor using some of the extraction solvents instantly claimed.

Mueller beneficially teaches the extraction of components from cocoa shells, whereby the cocoa shells are first ground prior to solvent extraction (see, e.g., page 754). The grinding of herbal parts including nuts and seeds prior to extraction, such as beneficially disclosed by Mueller, is notoriously well known in the art to advantageously facilitate the release of desired components therefrom during such solvent extraction by maximizing surface exposure.

Alander et al. beneficially teach that oils extracted from various herbals such as cocoa butter contain phytosterols, tocopherols, and tocotrienols which can be effectively extracted using suitable extraction solvents including nonpolar solvents such as hexane and petroleum ether (see, e.g., page 1, third paragraph; pages 7-8; page 10, third full paragraph).

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It would have been obvious to one of ordinary at the time the claimed invention was made to modify the extraction procedures taught by the primary reference in making a cocoa shell oil extract product via grinding the cocoa shells prior to solvent extraction based upon the beneficial teachings of Mueller with respect to this notoriously well known practice, and to use and/or substitute other suitable extraction solvents such as petroleum ether vs. hexane based upon the beneficially teachings provided by Alander et al. with respect to their equivalency as extraction solvents of cocoa butter which El-Saied et al. teaches is very similar to cocoa shell fat (thus, the skilled artisan would have a reasonable expectation of success in extracting cocoa shells using such equivalent solvents to obtained phytosterols - as well as tocals).

It would also have been obvious to the skilled artisan to utilize micronized cocoa hulls as a starting material because Newton beneficially discloses that micronizing is a commonly means of breaking the outer husks/hulls of cocoa beans during processing (see, e.g., col 5, lines 46-52), making them a readily available source. The adjustment of particular conventional working conditions (e.g., removing the solvent by vacuum distillation, further exposing such an oil extract to chromatographic techniques, using hulls from particular types of cocoa bean and/or from roasted or unroasted cocoa beans), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicants' arguments with respect to the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejection.

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Applicants argue that although the cocoa shell fat disclosed by El-Saied et al. reads upon a solidified oil, it does not mean they are identical; that fats and oils are very complex, and that they have different levels of the various natural constituents therein. However, as discussed in the previous Office action and above, cocoa shell (hull) oil is naturally present within such fat and, thus, cocoa shell (hull) fat is inherently comprised of cocoa shell (hull) oil. Further, there are no amount ranges for any of the recited constituents (e.g., for any of the recited free and bound phytosterols and tocopherols) within the instantly claimed cocoa hull oil. Accordingly, at least some of each of these naturally-occurring cocoa shell (hull) oil constituents would intrinsically be present within the cocoa shell oil-containing product disclosed by El-Saied et al.

Applicant further argues that the teachings of Baskakova et al. and Gavrilenko are not enabling. However, the skilled artisan could easily obtain cocoa husk (hull) oil such as that used within the cosmetic formulation taught by Baskakova et al. and/or that used within the oil refining process taught by Gavrilenko without undue experimentation and with a reasonable expectation of success via conventional art-recognized extraction techniques (including simply via pressing). Again, please note that such art-accepted cocoa husk (hull) oil would intrinsically contain the variously recited free and bound phytosterols and tocopherols therein since these are naturally-occurring constituents of cocoa husk (hull) oil - i.e., one of skill in the art would not reasonably conclude that the cocoa husk oils taught by Baskakova et al. and/or Gavrilenko would not contain these natural, inherent constituents.

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In addition, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicants' claimed invention fails to patentably distinguish over the state of the art represented by the references.

To hasten prosecution it is strongly suggested that independent claim 2 be amended so as to recite a product-by-process which appropriately incorporates the process steps recited in claim 15, as well as appropriately incorporates the limitations of either claim 7 or 8 therein; and that claim 15 be amended so as to recite a process of preparing a cocoa hull oil which appropriately incorporates the limitations of claim 2, as well as appropriately incorporates the limitations of either claim 7 or 8 therein. The cocoa oil product of claim 2 (containing all of the various ingredients recited therein) produced by the method of claim 15 (amended as such), whereby the cocoa hulls are from dried unfermented or fermented non-roasted cocoa beans (claim 8) or from micronized, non-roasted cocoa beans (claim 9), would adequately define and distinguish the instant invention over the prior art of record. To further hasten prosecution, it is suggested that claims 9, 11, 22, and all non-elected claims (claims 1, 12-14, and 24-28) be canceled in response to this Office action.

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Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654